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TITLE: DEVICE FOR SUBCUTANEOUS INFUSION OF FLUIDS

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# DEVICE FOR SUBCUTANEOUS INFUSION OF FLUIDS

## TECHNICAL FIELD

The technical field of this disclosure is medical devices, particularly for hydrating patients.

## BACKGROUND OF THE INVENTION:

Hypodermoclysis is a method of providing fluids to a patient that does not involve use of the intravenous or oral approaches. While often contraindicated for patients in severe dehydration, hypodermoclysis may be beneficial for palliative care, and may further be beneficial to a geriatric population. Hypodermoclysis is, in certain circumstances, less invasive than intravenous methods, and performance requires less skill than intravenous hydration.

One possible disadvantage of hypodermoclysis is the fluid flow rates possible. Because fluids do not disperse subcutaneously as quickly as in the vasculature, insertion sites are known to exhibit side effects including "camel humps" formed by fluid accumulation at the insertion site if the dispersion rate of the fluid in the subcutaneous tissue is less than the flow rate into the subcutaneous space. Thus, for a dehydrated patient, the hydration effects of hypodermoclysis treatment may be delayed as compared to intravenous treatment but the long-term results may be similar.

A variety of devices for non-intravenous hydration and therapeutic substance administration have been proposed. Wojcik, in United States Patent 6,572,586 discloses a low profile infusion set including a needle housing connected to a cannula housing. The needle housing has a pair of flexible sidewalls and a resilient band lockably engaged with the cannula. However, use of the Wojcik device is difficult due to angled insertion, and obtaining a desired fluid flow rate may require use of multiple devices. Mann discloses a similar device in United States Patent 6,254,586. The Mann device is relatively complex and provides a needle in communication with a cannula in the body of a base. Mann uses a sensor mounted at a skin site and directly monitors fluid flow.

Kriesel, United States Patent 5,858,005, discloses a device with similar fluid flow disadvantages, and is also relatively complex to manufacture. Livingston discloses a spring loaded subcutaneous injection set in United States Patent 5,584,813. However, the Livingston device inserts a cannula into the subcutaneous layer, which may be undesirable. Further, the Livingston device also suffers from the same fluid flow disadvantages.

Van Antwerp discloses a subcutaneous injection set with a crimp-free soft cannula in United States Patent 5,257,980. The Van Antwerp device inserts a cannula into the subcutaneous layer, and also has the same fluid flow limitations. Bartholomew discloses a subcutaneous injection set with improved cannula mounting arrangement in United States Patent 5,176,662. The Bartholomew device has many of the same fluid flow disadvantages, and further includes a complex apparatus that inserts a cannula into the subcutaneous space. Quick discloses a needle device for use with subcutaneous catheter assemblies at United States Patent 4,710,176. The Quick device comprises a needle inserted perpendicular to the skin, but has similar fluid flow limitations. Furthermore, the Quick device is relatively complex.

Kamen discloses a relatively simple infusion needle attachment in United States Patent 4,380,234. However, the Kamen device maintains the fluid flow disadvantages, and is difficult to insert due to the angled approach. While not as simple as the Kamen device, Feller Jr. discloses an intravenous infusion assembly in United States Patent 4,362,156. However, the Feller Jr. patent discloses an intravenous, rather than subcutaneous, device that is angularly delivered to the delivery site.

McFarlane discloses a relatively simple securing device for catheter placement assemblies in United States Patent 4,129,128. The McFarlane device includes a catheter assembly, and two wings joined by a body that includes an arch configured to press a catheter into the skin surface.

It would be desirable therefore to provide an apparatus and method that overcomes these, and other, problems.

## SUMMARY OF THE INVENTION

One embodiment of the invention provides a subcutaneous infusion device. The device includes a delivery tube including a central lumen, a closed first end and an open second end. The delivery tube is attached to a support base adjacent a first end of the delivery tube. A plurality of needles extend substantially perpendicular to the support base and in communication with the central lumen of the delivery tube.

Another embodiment of the invention provides a method for hydrating a patient. The method includes pressing a support base against a skin surface of the patient and inserting a plurality of needles into a subcutaneous skin layer responsive to the pressing. A saline fluid is delivered to the subcutaneous skin layer through the needles via a delivery tube.

Yet another embodiment of the invention provides a method for treating a skin ulcer. The method includes pressing a support base against a skin surface of the patient and inserting a plurality of needles into a subcutaneous skin layer responsive to the pressing. A saline fluid is delivered to the subcutaneous skin layer through the needles via a delivery tube.

The present invention is illustrated by the accompanying drawings of various embodiments and the detailed description given below. The drawings should not be taken to limit the invention to the specific embodiments, but are for explanation and understanding. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof. The foregoing aspects and other attendant advantages of the present invention will become more readily appreciated by the detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

**FIG. 1** illustrates a perspective view of one embodiment of a device used in accordance with the present invention;

**FIG. 2** illustrates a side view of the device illustrated in **FIG. 1** in a deployed position;

**FIG. 3** illustrates a top view of the device illustrated in **FIG. 1** in accordance with another aspect of the invention;

**FIG. 4** illustrates a side view of a device comprising more than 2 needles, in accordance with another embodiment of the invention;

**FIG. 5** illustrates a top view of a device comprising more than 2 needles, in accordance with another embodiment of the invention;

**FIG. 6** illustrates a top view of a device comprising more than 2 needles, in accordance with another embodiment of the invention;

**FIG. 7** illustrates a top view of a device comprising more than 2 needles, in accordance with another embodiment of the invention; and

**FIG. 8** illustrates a flowchart depicting one embodiment of a method for hydrating a patient in accordance with one embodiment of the invention.

## DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

**FIG. 1** illustrates a perspective view of a device for subcutaneous infusion of fluids in accordance with one aspect of the present invention. The device **100** includes a delivery tube **150**, a support base **175**, and a plurality of needles, **110**, **120**. The delivery tube includes a central lumen **105**, a closed first end **130** and an open second end **140**. Support base **175** includes an application side **136** and a side opposite **146** the application side.

Delivery tube **150**, in one embodiment, is a cannula. In another embodiment, delivery tube **150** is a catheter. In another embodiment, delivery tube **150** is any biomedically suitable delivery tube configured to deliver fluid to a delivery site. In one embodiment, delivery tube **150** is affixed to an opposite side **146** opposite the application side **136**. Lumen **105** is configured for fluidic communication with a fluid source (not shown) through the open first end **140**. The delivery tube **150** may be fixedly attached **145** to the opposite side **146**, or the delivery tube may be integral with the opposite side **146**. In one embodiment, the delivery tube **150** is adhesively affixed to the opposite side **146**.

Support base **175** is configured to provide support for the device **100** against a skin surface. **FIG. 1** illustrates support base **175** configured in a generally rectangular shape. In another embodiment, support base **175** is configured to be substantially circular. In another embodiment, support base **175** is configured as a triangle or other polygon. In one embodiment, support base **175** comprises vinyl, although any biomedically suitable substance may be used. In one embodiment, the support base **175** is a flexible support, while in another embodiment, the support base **175** is substantially rigid. In another embodiment, support base **175** is substantially planar.

In one embodiment, the open second end **140** comprises a female luer fitting. In another embodiment, the luer fitting includes a luer fitting cap. The open second end **140** is configured to be connected to a fluid source (not shown), such as an IV bag, to supply fluid to the needles. In one embodiment, the fluid is a saline fluid. In another embodiment, the fluid is therapeutic and includes pharmaceutical compounds intended to have a beneficial therapeutic effect on a patient.

Needles **110** include a lumen **112**. Lumen **112** is in fluidic communication with lumen **105** at a communication end **118** of the needle **110**. Communication end **118** is disposed within the lumen **105**. Needle **110** further includes a second open end disposed external to lumen **105**. The second open end is configured to penetrate skin and deliver a fluid from the lumen **105** into the subcutaneous space. In one embodiment, the communication end **118** is flush with the inner surface of the lumen **105**. In another embodiment, the communication end **118** is disposed within the lumen **105**. In yet another embodiment, needle **110** is angled within the lumen **105** and the communication end **118** is disposed within the lumen **105**.

Needles **110** may be sized based on treatment requirements. In one embodiment, needles **110** are 27 gauge needles, 6 millimeters long. In another embodiment, needles **110** are configured to provide a fluid flow rate of substantially 120 to 200 cc/hr. In another embodiment, needles **110** are configured to provide a flow rate of substantially 80 cc/hr.

In one embodiment, device **100** includes an adhesive **135** disposed upon the application side **136**. The adhesive **135** is any appropriate, biomedically compatible adhesive. Adhesive **135** is disposed upon the entirety of the application side **136**, in one embodiment. In another embodiment, adhesive **135** is disposed upon only a predetermined portion of the application side **136**.

**FIG. 1** further illustrates the device **100** adjacent a skin surface **195**. Also illustrated is a subcutaneous skin layer **198**.

**FIG. 2** illustrates a side view of the device illustrated in **FIG. 1** at **200**. Like numbers in **FIG. 2** illustrate like structures of **FIG. 1**.

**FIG. 3** illustrates a side view of the device illustrated in **FIG. 1** at **300**. Like numbers in **FIG. 3** illustrate like structures of **FIG. 1**.

**FIG. 4** illustrates a side view of one embodiment of a device **400** in accordance with another aspect of the invention. The device **400** is similar to the device **100** and includes additional needles **410**. Device **100** includes two needles **110**, while device **400** includes 6 needles **410**. It will be immediately apparent that a device in accordance with the invention can include any number of, but at least two, needles. Device **400** includes luer lock **440**, delivery tube **450** and support base **475**. In **FIG. 4**, needles **410** are configured in series.

**FIG. 5** illustrates a top view of the device illustrated in **FIG. 4** in accordance with one aspect of the invention.

**FIG. 6** illustrates a device **600** for hydrating patients in accordance with another aspect of the invention. Device **600** includes a substantially triangular support base **675** and a plurality of needles **610**. In the embodiment illustrated in **FIG. 6**, needles **610** are configured in parallel. In another embodiment, needles **610** are configured in series. Device **600** includes luer lock **640** and delivery tube **650** and other structures similar to the device **100**.

**FIG. 7** illustrates a device **700** for hydrating patients in accordance with another aspect of the invention. Device **700** includes a substantially circular support base **775** and a plurality of needles **710**. In the embodiment illustrated in **FIG. 7**, needles **710** are configured in parallel. In another embodiment, needles **710** are configured in series. Device **700** includes luer lock **740** and delivery tube **750** and other structures similar to the device **100**.

**FIG. 8** is a flowchart illustrating one embodiment of a method **800** for hydrating a patient in accordance with another embodiment of the invention. Method **800** begins at block **810** by pressing a support base against a skin surface of the patient. In one embodiment, the support base is a support base as illustrated in **FIGS 1**, **4**, **6** or **7**.

Method **800** continues at block **820** by inserting a plurality of needles into a subcutaneous skin layer responsive to the pressing. In one embodiment, the skin layer is in a fleshy area, such as, for example, an upper arm or thigh. In another embodiment, the skin layer is adjacent a skin ulcer.

Method **800** continues at block **830** by delivering a fluid to the subcutaneous skin layer through the needles via a delivery tube. In one embodiment, the fluid is a saline fluid. In another embodiment, the fluid is therapeutic and includes pharmaceutical compounds intended to have a beneficial therapeutic effect on a patient.

In this application, the terms "parallel" and "series" are ascribed a meaning similar to the meaning of those terms as applied in electronic circuits. Thus, needles configured in "parallel" have a common fluid source that divides to supply an individual needle, such as the embodiment illustrated in **FIG. 6**. Needles configured in series have a single fluid source for multiple needles, such as the embodiment illustrated in **FIG. 4**. Some embodiments of the invention may include needle configured in both series and parallel.

Practice of this invention allows for hydration of patients without intravenous approaches. Practice may also provide another method to treat skin ulcers by hydrating the skin surrounding the ulcer. Application of a growth hormone, or any other fluidic treatment regime, using the invention may be indicated under certain circumstances. Further, use of a plurality of needles in a single device allows for a greater variety of fluid flow levels.

Variations and alterations in the design, manufacture and use of the system and method are apparent to one skilled in the art, and may be made without departing from the spirit and scope of the present invention. While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalents are intended to be embraced therein.